IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF CALIFORNIA, COMMONWEALTH OF MASSACHUSETTS, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF MAINE, STATE OF MARYLAND, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NORTH CAROLINA, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, and STATE OF WISCONSIN, *Plaintiffs*, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II*, in his official capacity as Secretary of Health and Human Services*, and ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights at the United States Department of Health and Human Services*, *Defendants*.	No. 1:20-cv-5583

BRIEF OF THE INSTITUTE FOR POLICY INTEGRITY AT NEW YORK UNIVERSITY SCHOOL OF LAW AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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The Institute for Policy Integrity at New York University School of Law ("Policy Integrity") submits this brief as amicus curiae in support of Plaintiffs' Motion for a Preliminary Injunction of the final rule, Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Rule"), promulgated by the Department of Health and Human Services ("HHS" or the "Department").[1] The 2020 Rule rescinds and revises provisions of the Department's prior rule, Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) ("2016 Rule").

INTERESTS OF AMICUS CURIAE

Policy Integrity is a nonpartisan, not-for-profit think tank dedicated to improving government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy. In particular, Policy Integrity's staff of economists and lawyers has written extensively on the use of cost-benefit analysis in regulatory decisionmaking. Its director, Professor Richard L. Revesz, has published more than eighty articles and books, including many that address the legal and economic principles that inform rational agency decisions.

In furtherance of its mission, Policy Integrity has filed amicus briefs in numerous recent cases addressing economic analyses performed by administrative agencies. *See, e.g.*, Briefs for Institute for Policy Integrity as Amicus Curiae, *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42 (2d Cir. 2020) (No. 19-3595) (criticizing cost-benefit analysis underlying Department of Homeland Security's "public charge" rule for disregarding key health and welfare harms); *District of Columbia v. U.S. Dep't of Agriculture*, No. 20-119 (D.D.C. July 1, 2020) (arguing that agency failed to sufficiently evaluate health and welfare harms in restricting food-assistance benefits);

[1] This brief does not purport to represent the views, if any, of New York University School of Law. Policy Integrity states that no party's counsel authored this brief in whole or in part, and no person contributed money intended to fund the preparation or submission of this brief.

New York v. U.S. Dep't of Health & Human Servs., 414 F. Supp. 3d 475 (S.D.N.Y. 2019) (No. 19-cv-4676) (arguing that agency failed to fully assess health and welfare costs of rule permitting healthcare discrimination in certain circumstances). In many such cases, courts have agreed that the agency's analysis—and thus the rule relying on that analysis—was arbitrary and capricious for mischaracterizing or ignoring the costs of a regulatory rollback. *See, e.g.*, *New York*, 414 F. Supp. 3d at 546–56; *California v. U.S. Dep't of the Interior*, 381 F. Supp. 3d 1153, 1170 (N.D. Cal. 2019) (finding repeal arbitrary due, in part, to flawed economic impact assessment).

Policy Integrity also regularly files comments and testifies before federal and state agencies on proposed rulemakings. Of particular relevance here, Policy Integrity filed comments with the Department criticizing its assessment of the costs and benefits for the proposed version of the 2020 Rule. *See* Inst. for Pol'y Integrity, Comments on Proposed Rule (Aug. 13, 2019) ("Policy Integrity Comments").[2] In those comments, Policy Integrity argued that the Department failed to consider the proposal's considerable costs to patients—including both transgender patients who would be harmed by the proposal's nondiscrimination provisions and Limited English Proficient ("LEP") patients who would be harmed by its language-assistance rollbacks—and failed to support the conclusion that the proposal's benefits would justify its costs.

In line with Policy Integrity's past arguments against the 2020 Rule, Plaintiffs here contend that this rule is arbitrary and capricious under the Administrative Procedure Act because the Department fails to meaningfully assess or consider the widespread health and welfare harms that will result. Pls. Br. 41–65. Policy Integrity's expertise in cost-benefit analysis gives it a unique perspective from which to evaluate this claim.

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[2] *Available at* https://policyintegrity.org/documents/PolicyIntegrity_Section1557Comments_2019.08.13.pdf.

SUMMARY OF ARGUMENT

When an agency relies on a cost-benefit analysis as part of its rulemaking, a "fundamental flaw" undermining that analysis renders the rule unreasonable. *Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 57 (2d Cir. 2003). Such is the case here. While the Department repeatedly touts the cost savings that will allegedly flow from the 2020 Rule, it fails even to acknowledge the considerable social harm likely to accompany those savings, including reduced healthcare access and worse health outcomes among certain populations. This one-sided analysis renders the 2020 Rule arbitrary and unreasonable. *See id.* at 58 (rejecting "[t]he notion that 'cheapest is best'").

For one, the Department fails to recognize the substantial possibility that transgender and other LGBTQ individuals will face additional discrimination in healthcare settings[3]—and, as a result, experience lower access to care and attendant adverse health impacts—because of the 2020 Rule, brushing aside these effects as "minimal" with little analysis. 85 Fed. Reg. at 37,225. But discrimination against transgender and other gender-nonconforming individuals in the healthcare context "lead[s] to negative health consequences" such as higher risk of numerous diseases, as HHS previously recognized, 81 Fed. Reg. at 31,460, belying the Department's claim that withdrawing the 2016 Rule's protections will have minimal impact. And while HHS offers excuses for its failure to assess the 2020 Rule's harms, none are persuasive. Most notably, the Department stresses that some of the 2016 Rule's requirements were vacated by a federal court, 85 Fed. Reg.

[3] The 2016 Rule defined discrimination "on the basis of sex" to include discrimination on the basis of "gender identity" and "sex stereotyping"—protections that the 2020 Rule rescinds. *Compare* 81 Fed. Reg. at 31,467 *with* 85 Fed. Reg. at 37,167–68 (promulgating and subsequently repealing 45 C.F.R. § 92.4). And although the 2016 Rule did not expressly prohibit discrimination based on sexual orientation, the Department observed that the prohibition on sex-stereotype-based discrimination would likely protect LGBTQ individuals—including not only transgender individuals but also lesbian, gay, and bisexual persons—in particular circumstances. 81 Fed. Reg. at 31,389–90. Accordingly, while this brief focuses primarily on the harms to transgender individuals that will result from the 2020 Rule, it also refers to costs that removing "sex stereotyping" from the definition of "on the basis of sex" will impose on other LGBTQ individuals.

at 37,225, yet ignores the possibility that those obligations will be reinstated on appeal—a likely scenario following the Supreme Court's decision in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020)—and disregards the effects of the rescinded requirements that have not been vacated. The Department's failure to reasonably consider these substantial harms is incompatible with its obligation to pay "attention to the advantages *and* the disadvantages of [its] decisions." *Michigan v. EPA*, 576 U.S. 743, 753 (2015).

The Department's disregard for the social costs of repealing key language-access provisions of the 2016 Rule is equally problematic and unlawful. While the record indicates that this repeal will hamper treatment for many of the millions of LEPs in the United States and thus cause adverse health impacts for this population, the Department irrationally pays these harms virtually no attention, instead claiming that they elude estimation and are likely negligible. Making matters worse, by cataloguing in exacting detail the alleged cost savings of repealing the requirement that healthcare providers advise individuals in multiple languages of their right to language assistance (known as the "notice-and-tagline" requirement) while providing a bare-bones assessment of forgone benefits, the Department "inconsistently and opportunistically frame[s]" the 2020 Rule's impacts. *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011).

By repeatedly minimizing or ignoring the 2020 Rule's likely health and welfare costs, the Department arbitrarily puts a "thumb on the scale" in favor of this rule, *Ctr. for Biol. Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008), and fails to provide the "reasoned explanation" required under the Administrative Procedure Act for discarding its own past findings on the significant benefits of the 2016 Rule, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009). Because the Department relies on this flawed and lopsided analysis to justify the 2020 Rule, that rule is arbitrary and capricious.

ARGUMENT

Final agency actions are arbitrary and capricious under the Administrative Procedure Act, 5 U.S.C. § 706(2), if the agency fails to "examine the relevant data," "consider an important aspect of the problem," or "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted). Under this standard, a "serious flaw undermining" an agency's cost-benefit analysis "can render the rule unreasonable," *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012), even if that analysis was not legally required, *id.* at 1039–40.

Among other serious flaws that may undermine a cost-benefit analysis is a failure to consider costs, as agencies typically treat costs as a "centrally relevant factor when deciding whether to regulate," *Michigan*, 576 U.S. at 753. Costs in this context include far more than compliance-related financial expenditures: Rather, as the Supreme Court has explained, the concept of regulatory "cost" encompasses "any disadvantage" resulting from a rule, "including, for instance, harms that regulation might do to human health." *Id.* at 752.[4] And, in the case of a deregulatory rule such as this one, regulatory costs include the forgone benefits that were expected from the regulations being repealed. *See, e.g.*, *Air All. Hous. v. EPA*, 906 F.3d 1049, 1067–68 (D.C. Cir. 2018). Accordingly, courts have set aside rules, including deregulatory rules, when the issuing agency "inconsistently and opportunistically framed the costs and benefits of the rule; failed adequately to quantify the certain costs or to explain why those costs could not be quantified

[4] The primary executive order governing regulatory cost-benefit analysis likewise instructs agencies to consider harms to "health, safety, and the natural environment" in their cost assessments, in addition to "adverse effects on the efficient functioning of the economy." Exec. Order No. 12,866 § 6(a)(3)(C)(ii), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

. . . [or] failed to respond to substantial problems raised by commenters" regarding the regulatory impact analysis. *Bus. Roundtable*, 647 F.3d at 1148–49.

Here, as previewed above, the Department does not meaningfully consider the substantial social costs—including widespread harms to human health—that the 2020 Rule will likely impose on LGBTQ and LEP individuals by repealing protections in the 2016 Rule. This disregard for previously recognized benefits renders the 2020 Rule arbitrary and capricious.

I. The Department Disregards the 2020 Rule's Potentially Substantial Costs to Patients Harmed by the Rollback of Sex-Discrimination Provisions

The Department gives practically no consideration to the 2020 Rule's potentially substantial costs to transgender and other LGBTQ patients from the 2020 Rule's provisions rolling back nondiscrimination protections, failing to analyze the 2020 Rule's impacts on healthcare access and medical outcomes despite extensive analysis of these impacts in many comments and in the 2016 Rule itself.

The 2020 Rule includes several provisions that are likely to boost discrimination relative to the 2016 Rule baseline, including removing discrimination based on gender identity and sex stereotyping from the 2016 Rule's sex-discrimination protections, revoking the prohibition on categorically excluding health services related to gender transition, and imposing a broad religious exemption to these narrowed requirements. Indeed, the Department previously recognized that the 2016 Rule's nondiscrimination protections would likely produce "health improvements and longevity extensions as a result of reduced barriers to medical care," identifying this as a key benefit of that rule. 81 Fed. Reg. at 31,465. Yet now the Department finds that repealing such protections will have "minimal" adverse impacts in the form of forgone benefits, pointing to intervening case law and purported uncertainty about the scope and severity of the harm that may ensue. 85 Fed. Reg. at 37,225.

But as the record firmly establishes, the 2020 Rule is likely to cause far more than "minimal" harm to transgender and other LGBTQ patients. And for this reason, the Department's excuses for failing to acknowledge or consider the possibility or severity of these social costs ring hollow.

A. The 2020 Rule Likely Forgoes Substantial Health Benefits for Transgender and Other LGBTQ Individuals Relative to the 2016 Rule

The 2016 Rule's protections were widely expected to reduce discrimination against transgender and other LGBTQ individuals in the healthcare context, boosting treatment access and medical outcomes. Yet in rescinding these provisions in the 2020 Rule, the Department does not so much as acknowledge their previously anticipated effects, disregarding the substantial benefits likely being forgone from the elimination of these key protections.

As the Department recognized in its regulatory impact analysis for the 2016 Rule, transgender and other LGBTQ patients face widespread discrimination from doctors and insurance companies, leading them to "postpone or . . . not seek needed health care" and be "denied opportunities to obtain health care services." 81 Fed. Reg. at 31,444. This results in "adverse effects on the[] health" of affected individuals, the Department further recognized, "exacerbat[ing] health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer." *Id.* at 31,460. And these poor health outcomes harm the healthcare system more broadly, the Department concluded, causing "a marketplace comprised of higher medical costs due to delayed treatment" along with "lost wages, lost productivity, and the misuse of people's talent and energy." *Id.* at 31,444.

When the Department proposed to eliminate the sex-discrimination provisions of the 2016 Rule, many commenters, including esteemed national health organizations, echoed and elaborated

upon these previously cited impacts and emphasized the severe health-related costs likely to result from the 2020 Rule. With regard to the scope of healthcare discrimination, for instance, the American Heart Association explained that "70 percent of transgender and gender nonconforming people [] have been denied care or had a provider use harsh language or blame their sexual orientation as the cause for an illness." Am. Heart Assoc., Comments on Proposed Rule 5 (Aug. 13, 2019) ("AHA Comments").[5] Individuals who face discrimination from one provider may have difficulty receiving substitute care: For instance, 41 percent of LGBTQ individuals living outside a metropolitan area reported that it would be "not possible" or "very difficult" to obtain the same service at a different hospital. Ctr. for Am. Progress, Comments on Proposed Rule 8 (Aug. 13, 2019) ("CAP Comments").[6] As a result, many transgender and other LGBTQ individuals now forgo needed medical care. One study from Harvard University found that 18 percent of LGBTQ individuals "reported for[]going medical care, including preventive care, due to fears of discrimination," *id.* at 10—an effect amplified by the American Medical Association, Am. Med. Assoc., Comments on Proposed Rule 4 (Aug. 13, 2019) ("AMA Comments")[7] (reporting, based on another study, that "23 percent [of transgender individuals] did not seek health care when they needed it due to fear of being disrespected or mistreated as a transgender person").

These treatment discrepancies often lead to poor health results, exacerbating the medical inequalities that transgender and other LGBTQ individuals already face. The LGBTQ community is already "more at risk for certain conditions that require preventive or chronic care management, such as tobacco use or cardiovascular disease," AHA Comments at 5, and, as a group of doctors from Yale University School of Medicine explained, faces greater incidence of psychiatric

[5] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-147945.
[6] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-146956.
[7] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-137131.

disorders and substance abuse along with a higher risk of HIV/AIDS for gay and bisexual men, Andrea Barbieri, MD, et al., Comments on Proposed Rule 2–3 (Aug. 13, 2019).[8] As the American Heart Association explained, "[r]esearchers have found that these issues may be caused or exacerbated by LGBT individuals' anxiety about how they will be treated by primary care doctors and other health care stakeholders." AHA Comments at 5. Research on health outcomes for transgender individuals has "found that discrimination in health care settings was associated with increased risk of adverse emotional and physical symptoms," for instance, and established a causal link between discrimination in healthcare settings and substance use and attempted suicide. Nat'l Ctr. for Transgender Equality, Comments on Proposed Rule 18–19 (Aug. 13, 2019) ("NCTE Comments").[9]

Given the health risks that transgender and other LGBTQ individuals already face, reducing such patients' protections against discrimination, as the 2020 Rule does, will likely carry severe health consequences, including premature mortality. Assessing the impacts on delayed screenings for four of the most common types of cancer, for instance, Johns Hopkins University scholars concluded that the 2020 Rule "will cost $1.4 billion in excess costs over the next ten years to treat cases of these four cancers alone that would have been detected and prevented by screening," CAP Comments at 10–11, potentially causing dozens or hundreds of preventable deaths among individuals who lose out on early detection and treatment as a result of the 2020 Rule, NCTE Comments at 79. When considering impacts from all medical conditions beyond those cancers, the 2020 Rule's adverse effects would likely be substantially greater.

[8] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-150838.

[9] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-153312.

While healthcare-related discrimination against transgender people frequently concerns denials of care or coverage for broadly applicable procedures, such as mammograms or other screenings, AMA Comments at 4, transgender patients are also adversely impacted by refusals to treat gender dysphoria. Despite the conclusion of many "major medical organizations . . . that transition-related treatments are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria," NCTE Comments at 3, healthcare providers have frequently refused to provide this treatment, *id.* at 5, and, prior to the 2016 Rule, "many health-related insurance plans . . . ha[d] explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition," 81 Fed. Reg. at 31,429. Revoking that rule's prohibition on categorical coverage exclusions thus may cause the denial of this treatment to many individuals, imposing yet another cost on the transgender community.

In assessing the 2020 Rule's impacts, however, the Department analyzes none of these profound real-world health costs. With regard to transgender individuals, the Department states simply and with virtually no analysis that the 2020 Rule's effects "will be minimal," 85 Fed. Reg. at 37,225, without quantifying these impacts or otherwise assessing "how important [they] may be," Office of Mgmt. & Budget, Circular A-4 on Regulatory Analysis 2 (2003) ("Circular A-4"). Regarding other LGBTQ individuals, the Department "does not deem there to be an economic impact resulting from this final rule" since "the 2016 Rule contained no prohibition on sexual orientation discrimination." 85 Fed. Reg. at 37,238. The Department's minimal evaluation of the 2020 Rule's substantial health and welfare impacts on transgender and other LGBTQ individuals is a far cry from the "central[] relevan[ce]" that costs are normally given in agency decisionmaking, *Michigan*, 576 U.S. at 753, and presents a textbook example of arbitrary-and-capricious rulemaking.

B. The Partial Vacatur of the 2016 Rule Does Not Justify the Department's Full Disregard for that Rule's Benefits

The Department attempts to justify its failure to consider any forgone benefits of the 2016 Rule for transgender and other LGBTQ individuals by noting that the 2016 Rule's sex-discrimination provisions were partially vacated in *Franciscan Alliance v. Azar,* 414 F. Supp. 3d 928 (N.D. Tex. 2019), *appeal docketed*, No. 20-10093 (5th Cir. Jan. 24, 2020). 85 Fed Reg. at 37,225. This excuse fails. For one, because *Franciscan Alliance* neither vacated the 2016 Rule's prohibition on discrimination based on sex stereotyping nor imposed a broad religious exemption, it provides no basis for the Department to entirely ignore the harms to transgender and other LGBTQ individuals from the 2020 Rule's provisions regarding sex stereotyping and religious exemption. Moreover, given that *Franciscan Alliance* is on appeal and its reasoning was undercut by the Supreme Court's *Bostock* decision, the Department is unjustified in assuming that it would not forgo any benefits by repealing the 2016 Rule's provisions regarding gender identity.

While the Department cites *Franciscan Alliance* as the basis to avoid assessing any of the 2020 Rule's harms to transgender individuals, *id*. at 37,225, it overstates the import of that case and ignores key provisions of the 2020 Rule that the case did not address. While *Franciscan Alliance* vacated the 2016 Rule "insofar as [it] define[d] '[o]n the basis of sex' to include gender identity and termination of pregnancy," the "remainder of 45 C.F.R. § 92," including the prohibition on discrimination based on sex stereotyping, "remain[ed] in effect." Order, 414 F. Supp. 3d 928 (N.D. Tex. Nov. 21, 2019). Moreover, while the court found that the 2016 Rule violated the Religious Freedom Restoration Act as applied to the plaintiffs in that case, it did not mandate the broad religious exemption that the Department supplies in the 2020 Rule. *Franciscan All.*, 414 F. Supp. 3d at 944.

Accordingly, even assuming the *Franciscan Alliance* vacatur as part of the proper analytical baseline from which to determine the consequences of the 2020 Rule, that decision does not justify the Department's total disregard for the harms from the 2020 Rule's broad religious exemption and removal of protections against sex-stereotyping discrimination. Yet as the Department explained in the 2016 Rule, those two regulatory provisions themselves limit access to healthcare and promote discrimination against the LGBTQ community, including transgender individuals. For one, prohibitions on sex stereotyping often protect LGBTQ individuals from discrimination, 81 Fed. Reg. at 31,389–90, meaning that removing this provision would presumably subject many such individuals to discrimination and thereby result in the denial of treatment. A blanket religious exemption could likewise "result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care," the Department further recognized in the 2016 Rule, "with serious and, in some cases, life threatening results." *Id.* at 31,380. By failing to account for these previously-recognized harms to LGBTQ individuals in the 2020 Rule, the Department does not engage in reasoned decisionmaking.

While the Department's disregard for the harms from those two provisions is unreasonable by itself, its reliance on *Franciscan Alliance* as grounds for ignoring harms from the 2020 Rule's rescission of anti-discrimination protections based on "gender identity" is also arbitrary. As a preliminary matter, the Department's proposed version of the 2020 Rule—which, unlike the final rule itself, was issued before *Franciscan Alliance* was decided[10]—also omitted any meaningful

[10] Although the court in *Franciscan Alliance* had previously issued a preliminary injunction barring the Department from enforcing the 2016 Rule's prohibition on discrimination based on gender identity, 227 F. Supp. 3d 660 (N.D. Tex. 2016), the Department acknowledged that repealing that definition would still have effects on the regulated community and did not rely on this injunction as its basis for generally disregarding the impacts on transgender individuals. *See* 84 Fed. Reg. at 27,876 (projecting that the proposed rule, if finalized, would cause some "covered entities [to] revert to the policies and practices they had in place before" the 2016 Rule, and thus such entities would "no longer incur labor costs pursuant to the [2016 Rule] associated with

analysis of the health and welfare harms that would befall transgender individuals absent key nondiscrimination provisions in the 2016 Rule. *See* Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846, 27,876 (proposed June 14, 2019) (stating in passing that the Department "lacks the data necessary to estimate" the proposal's harms on this front and "seek[ing] comments" on the issue). This disregard for a major regulatory cost at the proposal stage—which, as Policy Integrity advised HHS, lacked empirical or legal justification, Policy Integrity Comments at 2–4—stands in tension with the Department's claim, 85 Fed Reg. at 37,225, that the 2020 Rule will not harm transgender individuals because of the intervening decision in *Franciscan Alliance*.

In any event, *Franciscan Alliance* does not support the Department's complete failure to acknowledge the 2020 Rule's health and welfare costs on transgender individuals, due to two other judicial events that occurred before the 2020 Rule was issued. First, the district court's order was appealed to the U.S. Court of Appeals for the Fifth Circuit. *See Franciscan All. v. Azar*, No. 20-10093 (5th Cir. docketed Jan. 24, 2020). And second, while that appeal was pending, the Supreme Court decided in *Bostock* that discrimination "because of such individual's . . . sex" encompasses discrimination on the basis of gender identity, 140 S. Ct. at 1738, 1754 (citing 42 U.S.C. § 2000e-2(a)(1)), which, as plaintiffs indicate, undercuts the district court's rationale in *Franciscan Alliance*, Pls. Br. 36–38. In light of these two events—both occurring before the 2020 Rule was issued—it was certainly plausible, if not likely, that the district court order would be overturned and the 2016 Rule's inclusion of gender identity would be restored.

processing grievances related to sex discrimination complaints as they relate to gender identity under Title IX because such claims would not be cognizable").

In such circumstances when "more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs"—like here, depending on whether or not the partial vacatur of the 2016 Rule would be affirmed or reversed—the Office of Management and Budget advises agencies to "measur[e] benefits and costs against alternative baselines," including baselines "reflecting a different interpretation of existing regulatory requirements." Circular A-4 at 15. The Department's internal guidance on economic analysis echoes this instruction, urging analysts to "consider modeling more than one baseline" when "future conditions are uncertain and changes in baseline assumptions significantly affect the analytic results." HHS, Guidelines for Regulatory Impact Analysis 7 (2016).[11] Rather than follow this regular practice, the Department "create[s] a false sense of precision," Circular A-4 at 40, by assuming the baseline that minimizes the 2020 Rule's costs while blinding itself to the likely alternative that this rule will impose severe harm on transgender individuals. "Blinders may work for horses, but they are no good for administrative agencies." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 924 (D.C. Cir. 2017) (criticizing agency's failure to recognize prior policy and thereby apply proper regulatory baseline).

While the 2020 Rule itself ignores the *Bostock* decision, the Department has argued in other litigation challenging the rule that "the [2020] Rule's language may be interpreted in conformity with *Bostock*," appearing to suggest that the 2020 Rule's more generic definition of "on the basis of sex" could be interpreted in line with the 2016 Rule's clear and inclusive sex-discrimination provisions. Brief for Defendants at 17, *Whitman-Walker Clinic v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-01630-JEB (D.D.C. July 24, 2020). Even assuming this is true, it hardly means that the 2020 Rule is costless on this front. Regulatory ambiguity could create "public confusion

[11] *Available at* https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.

regarding complainants' rights and covered entities' legal obligations," as the Department recognizes in a related context, 85 Fed. Reg. at 37,222, and as a result some covered entities "might change their policies," *id.* at 37,225, in a manner that increases discrimination. The possibility of confusion is particularly high due to the Department's claims in the preamble that the 2020 Rule captures discrimination only "on the basis of the fact that an individual is biologically male or female," *id.* at 37,178, which stands at odds with its suggestion in related litigation that the 2020 Rule be interpreted consistently with *Bostock*. Furthermore, if the Department truly expects no changes in the application of sex-discrimination protections from the 2016 Rule, then the 2020 Rule would necessarily lack any benefits on this front. The Department offers no reason as to why in this case a cosmetic redefinition that may sow confusion would be "worth the benefits sacrificed" from the 2016 Rule's clear and instructive definition, *Mineta*, 340 F.3d at 58, nor any explanation for how in this case the 2020 Rule would not "do[] significantly more harm than good," *Michigan*, 576 U.S. at 752.

In short, it is highly plausible that a reviewing court would have reversed the district court's order and restored the 2016 Rule's inclusion of gender identity in defining sex discrimination. Claiming that it causes no harm to preemptively rescind that provision is therefore illogical. In reality, there is a real likelihood that the 2020 Rule will lead to worse care and health outcomes for transgender and other LGBTQ patients that were protected by the 2016 Rule's inclusive provisions. And because the Department "entirely fail[s] to consider [this] important aspect of the problem," its action is arbitrary and capricious. *State Farm*, 463 U.S. at 43.

C. The Department's Claims of Uncertainty Are Also Unavailing

The Department also claims that it lacks information to assess the 2020 Rule's impacts on the transgender and LGBTQ populations. But this claim stands in tension with the Department's assertion that the rule's will cause only "minimal" harm to transgender individuals, 85 Fed. Reg.

at 37,225, and no impact on other members of the LGBTQ community, *id.* at 37,238. Moreover, the Department undersells the available data, and, in any event, cannot cite a lack of perfect information as a basis for disregarding the harmful consequences of its action.

The Department first alleges that it "knows of no data showing that [the 2020 Rule] will disproportionately burden individuals on the basis of . . . gender identity," 85 Fed. Reg. at 37,182, but this statement makes little sense in light of the voluminous data—both recognized by the Department in the 2016 Rule and provided by commenters to this rule—showing the high levels of healthcare discrimination faced by transgender individuals and resulting in disparate health outcomes. Indeed, the Department itself undercuts this claim when it recognizes that commenters provided quantitative estimates of the impacts of "increases in the denial, delay, or substandard delivery of healthcare services from the rule's changes concerning gender identity." *Id.* at 37,225.

The Department nonetheless dismisses the data provided, claiming that "commenters did not provide, and the Department is not otherwise aware of, reliable data or methods to calculate the economic impacts concerning gender identity that they allege would be attributable to [the 2020 Rule]." *Id.* at 37,238. But this does not absolve the Department of its obligation to assess the rule's harms. For one, while commenters can supply data to inform an agency's analysis, the Department bears the ultimate burden of supplying "a satisfactory explanation for its action," *State Farm*, 463 U.S. at 43, including due consideration of "relevant factors" like social costs, *id.* at 42.

Here, commenters established a clear link between protection against discrimination based on gender identity and sex stereotyping and beneficial health effects. Rather than offhandedly disregard this data, the Department should have used it to reasonably estimate the "magnitude" and "importan[ce]" of the 2020 Rule's impacts on discrimination and adverse health outcomes. Circular A-4 at 27. The Department's failure to "examine the relevant data," *State Farm*, 463 U.S.

at 43, and reach any meaningful conclusions about the 2020 Rule's costs to the transgender and LGBTQ communities violates its regulatory obligations.

The lack of perfect information does not justify this failure. Even assuming the Department lacked "sufficient quantitative evidence" to "estimate" the 2020 Rule's precise impacts, 85 Fed. Reg. at 37,238, it should nonetheless have "analyze[d] uncertainty" and used "plausible assumptions" to analyze the effects of the 2020 Rule, Circular A-4 at 38–39, allowing it to assess "how important the[se] . . . costs may be in the context of the overall analysis" including a comparison to any identified regulatory benefits, *id.* at 2. The Department's approach—citing data uncertainty to justify forgoing any detailed analysis or in-depth consideration, 85 Fed. Reg. at 37,225—falls well short of this standard. While there may be "a range of [plausible] values" for the 2020 Rule's extensive harms, the Department's assertion that these effects are effectively "too uncertain . . . [for] valuation and inclusion" impermissibly assigns them "zero" value. *Ctr. for Biological Diversity*, 538 F.3d at 1200 (internal quotation marks omitted).

In brief, "[r]egulators by nature work under conditions of serious uncertainty," and "[t]he mere fact that the magnitude of [a regulatory cost] is uncertain is no justification for disregarding the effect entirely." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1219, 1221 (D.C. Cir. 2004) (emphasis omitted). The Department's failure to meaningfully assess the 2020 Rule's likely significant costs on transgender and other LGBTQ individuals thus renders this rule arbitrary and capricious.

II. The Department Fails to Meaningfully Consider the 2020 Rule's Harms to LEP Patients

While the Department's disregard for the 2020 Rule's costs to transgender and other LGBTQ patients is itself arbitrary and capricious, the Department's examination of the 2020

Rule's costs to LEP patients from the removal of language-access provisions is similarly cursory and supplies another ground to vacate the rule.

As with transgender and other LGBTQ patients, the 2016 Rule was anticipated to bolster access to healthcare and thereby improve health outcomes for LEP patients by removing barriers that LEP individuals face in receiving regular and adequate healthcare. Yet while the Department now cites avoided compliance costs as grounds for rescinding these provisions, it fails to meaningfully acknowledge or closely evaluate the accompanying forgone benefits.

A. The 2020 Rule Forgoes Health and Welfare Benefits to LEP Individuals Relative to the 2016 Rule, Which the Department Irrationally Disregards

Considerable evidence and the Department's prior findings indicate that the 2020 Rule may cause extensive harms to the LEP community from the rescission of notice-and-tagline provisions. Yet the Department pays these harms virtually no attention and attempts to diminish their significance through cherry-picked and misleading statistical examples that miss the broader picture.

The Department's findings from the 2016 Rule are once again instructive, and clearly illustrate the Department's own prior view that this rule would benefit the country's millions of LEPs. As the Department then explained,"[s]tudies show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care." 81 Fed. Reg. at 31,459. Yet "when reliable language assistance services are utilized, patients experience treatment-related benefits," such as "enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance." *Id.* (citing research from the Institute of Medicine and other medical organizations). Accordingly, the Department concluded that the 2016

Rule's notice-and-tagline provisions would improve health outcomes for LEP individuals and "benefit both patients and providers alike." *Id.*

In response to the proposed repeal of the LEP provisions, commenters provided additional evidence and detail behind these impacts, explaining that the 2020 Rule would burden LEP individuals and worsen health outcomes. As the American Heart Association explained, LEP patients have "longer hospital stays when professional interpreters are not used at admissions," while also facing "a greater risk of surgical delays due to difficulty understanding instructions; and a greater chance of readmission for certain chronic conditions." AHA Comments at 10. While "barriers to care . . . exacerbate [these] existing health disparities," *id.* at 2, surveys conducted before the 2016 Rule took effect found that "while nearly 97 percent of doctors have non-English speaking patients, only 56 percent of hospitals . . . offered language access services," CAP Comments at 6. Returning to that pre-2016 Rule landscape would therefore likely "lead to negative, costly, and sometimes deadly consequences," the American Academy of Pediatrics concluded, highlighting one instance in which miscommunication with an LEP patient led to "medication being placed in the ear instead of taken by mouth, resulting in paralysis and a $71 million lawsuit." Am. Acad. of Pediatrics, Comments on Proposed Rule 6 (Aug. 13, 2019).[12]

Yet despite the extensive evidence of the value of healthcare access for LEP populations, the Department fails to acknowledge that the 2020 Rule's rollback of notice-and-tagline provisions will result in any health or welfare costs to this population, and indicates that such impacts are likely minimal. The Department's explanations here strain credulity. First, while the Department recognizes reports of "an increase in translation services after the 2016 Rule," it immediately and inexplicably discards these findings in favor of contrary findings from affected entities "that

[12] *Available at* https://www.regulations.gov/document?D=HHS-OCR-2019-0007-139520.

utilization of translation services did not appreciably rise after" the 2016 Rule. 85 Fed. Reg. at 37,233. The Department's arbitrary prioritization of data that minimizes the 2020 Rule's costs represents a "complete failure to reasonably . . . grapple with contrary evidence." *Sierra Club v. U.S. Dep't of the Interior*, 899 F.3d 260, 293 (4th Cir. 2018) (internal quotation marks omitted). "Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking." *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020).

The Department next cherry-picks statistics to support its claim that the 2020 Rule's impacts will be modest, even though these statistics, when properly contextualized, actually support the opposite conclusion. For instance, the Department notes a limited number of instances (fewer than one per state) in which the 2016 Rule "required health insurance issuers to provide taglines services in languages spoken by very few people," 85 Fed. Reg. at 37,233, yet fails to acknowledge the many more instances in which tagline provisions stood to benefit large numbers of LEP individuals. The Department also emphasizes that "[t]he vast majority of recipients of taglines do not require translation services," noting that "almost 80% of the recipients likely speak only English at home." *Id*. But this characterization is misleading, since a "portion of a gargantuan" total—such as the entire U.S. adult population—may itself "constitute[] a gargantuan" figure, and does so here. *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1032 (5th Cir. 2019) (internal quotation marks omitted). Viewed in proper context, this statistic means that tens of millions of LEP individuals stood to benefit from the 2016 Rule's notice-and-tagline provisions—indicating that this Rule, by repealing those provisions, may impose considerable harm.

The Department's disregard for that harm lacks rational justification. And because agencies typically cannot "ignore [the] cost" of a rule, *Michigan*, 576 U.S. at 753, this failure renders the rescission arbitrary and capricious.

B. The Department Presents a Lopsided Analysis By Painstakingly Cataloguing Alleged Cost Savings While Paying Virtually No Attention to Ensuing Health and Welfare Harms

While HHS's failure to meaningfully evaluate the potentially severe harm that may befall LEP individuals is unlawful by itself, the Department compounds its error by quantifying and monetizing alleged cost savings from the repeal of notice-and-tagline requirements in exacting detail and then claiming, without much analysis, that these savings justify any benefits forgone. It is precisely this type of imbalanced assessment that the Administrative Procedure Act forbids.

The Department devotes five Federal Register pages to assessing the cost savings from the removal of notice-and-tagline requirements, 85 Fed. Reg. at 37,227–32—far beyond the space that it devotes to assessing the corresponding harms. Among the various cost savings assessed are avoided expenditures on "toner, developer, paper, and postage." *Id.* at 37,231. Indeed, the Department spends a full page detailing the alleged savings to industry from postage costs alone, *id.* at 37,230—nearly the same amount of space that the Department devotes to assessing all of the forgone benefits to the LEP population.

The Department's assessments of cost savings and forgone benefits differ not merely in quantity, but in quality as well. When estimating cost savings, the Department evaluates data and makes assumptions: To assess alleged postage cost savings, for instance, the Department makes detailed assumptions about such factors as the number of sheets of paper required per mailing and the prevalence of electronic billing. *Id.* Yet when assessing forgone benefits, the Department does the opposite, bemoaning "the difficulty of attempting to calculate the 2016 Rule's benefits to individuals needing translation services." *Id.* at 37,223. But alleged uncertainty about these harms fails to justify the Department "*disregarding* the effect entirely," *Pub. Citizen*, 374 F.3d at 1219, as detailed above, and radically conflicts with the Department's approach to assessing cost savings.

Contrasted with its bare-bones look at forgone benefits, the Department's extensive assessment of alleged cost savings "inconsistently and opportunistically frame[s] the [2020 Rule's] costs and benefits," *Bus. Roundtable*, 647 F.3d at 1148–49, and cannot support its conclusion that those savings justify the corresponding harms. Agencies cannot "put a thumb on the scale by undervaluing the benefits . . . of more stringent standards," *Ctr. for Biological Diversity*, 538 F.3d at 1198, yet the Department's lopsided assessment of the 2020 Rule's impacts on LEP patients does precisely that. For this reason as well, the 2020 Rule is arbitrary and capricious.

CONCLUSION

This Court should grant Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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